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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,097	11/04/2005	Ralf-Christian Schlothauer	14923.0024	7026
27890 7590 09/14/2009 STEP TOE & JOHNSON LLP 1330 CONNECTICUT AVENUE, N.W. WASHINGTON, DC 20036				
EXAMINER				
TONGUE, LAKIA J				
ART UNIT		PAPER NUMBER		
1645				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/521,097

Applicant(s)

SCHLOTHAUER ET AL.

Examiner

LAKIA J. TONGUE

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 May 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 7-9, 13-22, 24, 27-29, 32-34 and 44-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 3, 49 and 50 is/are allowed.
- 6) ☒ Claim(s) 1, 2, 7-9, 13-22, 24, 27-29, 32-34 and 44-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-848)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Applicant's response filed on May 19, 2009 is acknowledged. Claims 1, 2, 8, 9, 21 and 29 has been amended. Claim 26 has been canceled. Claims 48-50 have been added. Claims 1-3, 7-9, 13-22, 24, 27-29, 32-34 and 44-50 are pending and under consideration.

Declaration

1. The declaration by Andrew John Morgan filed May 19, 2009 has been considered.

Objections Withdrawn

2. In view of Applicant's amendment, the objection to claim 1 for reciting in part, comprising an viable lactic acid microorganism and being grammatically incorrect is withdrawn.
3. In view of Applicant's amendment, the objection to claim 2 under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is withdrawn.
4. In view of Applicant's amendment, the objection to claim 8 under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is withdrawn.

5. In view of Applicant's amendment, the objection to claims 24 and 26 under 37 CFR 1.75 as being a substantial duplicate thereof is withdrawn. The cancellation of claim 26 renders the objection of said claim moot.

Rejections Withdrawn

6. In view of Applicant's amendment, the rejection of claims 1, 3, 7-9, 15-17 and 19-20 which were directed to non-statutory subject matter and read on a product of nature is withdrawn.

7. In view of Applicants submission of receipts and the corroborating declaration of deposits, the rejection of claims 1-3, 7-9, 13-22, 24, 26-29, 32-34 and 44-47 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is withdrawn. The cancellation of claim 26 renders the rejection of said claim moot.

8. In view of Applicant's arguments, the rejection of claims 1-3, 7-9, 13-22, 24, 26-29, 32-34 and 44-47 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the use of the phrase "comprising an viable lactic acid microorganism, an enzyme synthesized by said microorganism and an

exopolysaccharide produce of said enzyme", the terms "concentrated form", the term "component", and the use of the terms "functional food" is withdrawn.

Rejections Maintained

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. The rejection of claims 1, 2, 7-9, 13-22, 24, 27-29, 32-34 and 44-48 under 35 U.S.C. 112, first paragraph, as previously applied to claims 1-3, 7-9, 13-22, 24, 26-29, 32-34 and 44-47, as failing to comply with the written description requirement because the claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained for the reasons set forth in the previous office action. The removal of claim 3 from this rejection and the cancellation of claim 26 renders the rejection of said claims moot.

Applicant argues that:

1) It is clear from the Examples that by culturing *Lactobacillus sakei* strain 570 in the medium, exopolysaccharide are produced and the amount of EPS varies depending on the nature of the culture medium and the culture conditions.

2) The skilled artisan does not need to know the types of enzymes the microorganism produces in order to work the invention.

Applicant's arguments have been considered and are deemed non-persuasive.

The rejected claims are drawn to a composition for consumption, said composition comprising an isolated viable lactic acid microorganism, an enzyme synthesized by said microorganism and an exopolysaccharide (EPS) product of said enzyme; wherein said microorganism is *Lactobacillus sakei* strain 570.

With regard to Point 1, the Examiner does not negate that by culturing *Lactobacillus sakei* strain 570 in the medium, exopolysaccharide are produced and the amount of EPS varies depending on the nature of the culture medium and the culture conditions. However, the specification is required to describe a representative member of the claimed genus, which shares a particularly defining feature common to at least a substantial number of the members of the claimed genus, which would enable the skilled artisan to immediately recognize and distinguish its members from others, so as to reasonably convey to the skilled artisan that Applicant has possession the claimed invention. Although the specification demonstrates that EPS can be produced when cultured, the specification does not demonstrate possession of all EPS's or enzymes that can be produced when *Lactobacillus sakei* strain 570 is cultured.

With regard to Point 2, the claims are essentially drawn to a composition comprising an isolated viable lactic acid microorganism, an enzyme synthesized by said microorganism and an exopolysaccharide (EPS) product of said enzyme. Contrary to Applicant's assertion, the claims lack written description because of the phrase "an exopolysaccharide product of said enzyme". The specification is silent with regard to which enzymes are synthesized by the claimed microorganism or the EPS produced by

said enzyme. The specification is required to describe a representative member of the claimed genus, which shares a particularly defining feature common to at least a substantial number of the members of the claimed genus, which would enable the skilled artisan to immediately recognize and distinguish its members from others, so as to reasonably convey to the skilled artisan that Applicant has possession the claimed invention.

As previously presented, the claims are drawn to a vast genus of enzymes synthesized by said microorganism and an exopolysaccharide (EPS) produced by said enzyme. The specification is equally silent with regard to which EPS is capable of being modulated (see claim 15) and which EPS has the ability to improve the texture, body, mouth feel, viscosity, structure and/or organoleptic properties of a food containing said EPS as an ingredient (see claim 17). Further, the specification is silent with regard to which EPS has the capacity to reduce the production of gas by the gastrointestinal microorganism when used as ingredients to products for consumption.

To fulfill the written description requirements set forth under 35 USC § 112, first paragraph, the specification must describe at least a substantial number of the members of the claimed genus, or alternatively describe a representative member of the claimed genus, which shares a particularly defining feature common to at least a substantial number of the members of the claimed genus, which would enable the skilled artisan to immediately recognize and distinguish its members from others, so as to reasonably convey to the skilled artisan that Applicant has possession the claimed invention.

Finally, *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398, 1404. 1405 held that: "...To fulfill the written description requirement, a patent specification must describe an invention and does so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of the claimed antigenic outer membrane protein or an immunogenic fragment thereof, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel*, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993).

The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the "written description" inquiry, whatever is now claimed.

Therefore, absent a detailed and particular description of a representative number, or at least a substantial number of the members of enzymes and EPS, the skilled artisan could not immediately recognize or distinguish members of the claimed genus. Therefore, because the art is unpredictable, in accordance with the Guidelines, the description of a composition comprising a viable lactic acid microorganism, an enzyme synthesized by said microorganism and an exopolysaccharide (EPS) product of said enzyme; wherein said microorganism is *Lactobacillus sakei* strain 570 is not deemed representative of the genus of immunogenic compositions to which the claims refer and hence do not meet the written description requirements.

Conclusion

10. Claims 3, 49 and 50 are allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAKIA J. TONGUE whose telephone number is (571)272-2921. The examiner can normally be reached on Monday-Friday 8-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert B Mondesi/
Supervisory Patent Examiner,
Art Unit 1645

LJT
9/9/09

